TESTIMONY OF
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before the
SUBCOMMITTEE ON COMMERCE, TRADE, and CONSUMER PROTECTION
of the
COMMITTEE ON ENERGY and COMMERCE
U.S. HOUSE OF REPRESENTATIVES
Feb. 26, 2009

My name is J. Clarence Davies. I am a Senior Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars and a Senior Fellow at Resources for the Future. Neither the Wilson Center nor RFF take institutional positions on public policy matters, so the opinions expressed in my testimony are my personal opinions and do not represent the views of those organizations or their funders.

Let me start by commending the subcommittee for holding this hearing. The committee's focus on the Toxic Substances Control Act (TSCA) is timely because of changes taking place both at the state level and internationally. At the state level there have been a variety of new initiatives dealing with toxics. Internationally, the European Union's launch of the REACH directive has radically changed the requirements for any company wanting to market chemicals in Europe.

I believe this hearing could represent a turning point in the history of TSCA. For many years the chemical industry and EPA have agreed that TSCA is adequate to protect the public from the risks of chemicals despite much evidence to the contrary. That agreement, I think, no longer holds, and this hearing will provide solid evidence that TSCA is not functioning adequately and that changes are necessary.

I have followed TSCA from its inception. In 1969 I wrote a book which called for a law regulating new chemicals. In 1970, as a staff member with the newly formed Council on Environmental Quality, I wrote the original version of what became TSCA. I was not completely happy with the bill that emerged from the administration, and the intervening years have only strengthened my concerns about TSCA's flaws.

In the past several years, working with the Wilson Center, I have focused my attention on nanotechnology. I have written three reports on oversight of nanotechnology. Each of them is relevant to the subject of this hearing and I would like permission to

submit them for the record. Nanotechnology reveals many of TSCA's longstanding flaws and poses some new challenges. TSCA is the only existing law that can deal with nanotechnology generally. I will today discuss how shortcomings of TSCA that apply to all chemicals also apply to nano, and I will describe how trying to regulate nano has shown some TSCA problems that are unique to nano.

Before dealing with TSCA's weaknesses, let me note some good things about TSCA, things that should be preserved in any efforts to revise the law. First is the broadness and potential flexibility of the law. Its coverage is not limited to any one part of the environment and this is a definite asset because most chemicals are not limited to air or water or land but can travel from one part of the environment to another. TSCA also allows EPA to take a broad range of measures to deal with potential chemical problems. In theory, it gives the agency the flexibility to cope with new problems and unanticipated situations, although in practice this has not been the case.

The reporting mechanisms in TSCA also are valuable. Section 8(e), which requires manufacturers to immediately notify EPA of new information that supports the conclusion that a chemical may be a substantial risk, is particularly important. It allows EPA to adapt to new threats and to remedy problems caused by adverse effects that were overlooked in previous reviews of a chemical. Other sections of the act also contain useful reporting tools.

I would argue that the general cost-benefit framework of TSCA needs to be preserved. The law deals with useful products, not with pollutants. Because of this, decisions about regulating chemicals involve making trade-offs. Products, by definition, have benefits, so limiting their use or banning them to prevent adverse health or environmental effects almost always has some costs. This fact makes an absolute safety standard unwise because the government would be forced to ban chemicals that do more good than harm.

Many of the good things in TSCA are undermined by the procedural land mines scattered throughout the act. The act contains a number of very difficult, perhaps impossible, requirements that must be met before a chemical can be regulated. For example, EPA must show that the proposed regulation is less burdensome than any alternative and that the risk could not be sufficiently reduced under some other law. All

the requirements must be "supported by substantial evidence in the rulemaking record," an extraordinarily high legal hurdle. Court decisions have demonstrated that the combination of the difficult requirements and the high legal hurdle make it practically impossible for EPA to regulate existing chemicals under TSCA (*Corrosion Proof Fittings v. EPA).* Only if a chemical is considered a new chemical is EPA able to review its risk and perhaps impose limits on it.

Just as damaging as the procedural traps is TSCA's implicit assumption that no knowledge or no data is equivalent to no risk. This is epitomized in the "Catch 22" contained in TSCA section 5(e). It states that if EPA does not have enough information "to permit a reasoned evaluation of the health and environmental effects of a chemical," the agency can delay or prohibit manufacture of the chemical only if it can show that the chemical "may present an unreasonable risk" – which is precisely the thing the agency cannot show. There is another criterion that in theory can be used for EPA action. This is that the chemical will be produced in "substantial quantities" and that there will be significant environmental or human exposure. In practice, this criterion only rarely can be used, because most new chemicals initially are produced in small volumes, and because the likelihood of significant exposure is difficult to establish. The problem is even greater for nanomaterials because quantity or volume may not be a relevant indicator of potential risk.

In the long list of TSCA problems, a third area that needs to be noted is confidential business information (CBI). The act makes it very easy for manufacturers to classify information as CBI. As a result, a very large portion of all information submitted under the act is classified as confidential. The act then prohibits sharing of confidential information with states or with foreign governments. The result is that TSCA is less conducive to state-federal cooperation than any other environmental statute. The CBI provisions also are a major impediment to cooperating with other nations or international organizations. There is, I think, widespread agreement that TSCA's CBI provisions need to be changed.

Turning specifically to nanotechnology, nanomaterials are chemicals, so TSCA covers nanomaterials to the extent that they are not covered by other laws (such as the Food, Drug and Cosmetic Act or the federal pesticide law). Nanotechnology is the

science and application of manipulating matter at the scale of individual atoms and molecules. All natural processes, from the growth of human embryos to plant photosynthesis, operate in this way, but only recently have we developed the tools that allow us to build and analyze things at the molecular level. Nanotechnology's potential applications are boundless in scope and promise, and it is already being applied in hundreds of ways ranging from drugs to chemical catalysts to sports equipment.

As with most significant technologies, nano has potential costs as well as benefits. To date, there have been no documented cases of adverse health or environmental effects from nanotechnology. However, everything we know about nanomaterials leads to the conclusion that there is the potential for such adverse effects to occur. Nanomaterials generally are more biologically and chemically active than their bulk counterparts and can reach places in the environment and the human body that larger materials cannot. Very few resources have been devoted to investigating the health and environmental effects of nanomaterials, but the studies that have been done support the need to be concerned about nano's potential adverse effects. For example, a recent study on rats has shown that some kinds of carbon nanotubes (one of the most widely used nanomaterials) produce the same kind of pre-cancerous lung irritation that asbestos causes in humans.

EPA estimates that it has received notice of about 50 nanomaterials under TSCA's new chemicals provisions. The agency cannot be sure of this because its interpretation of TSCA's definition of a chemical excludes size. Because size is a defining factor in what is a nanomaterial, the agency cannot be sure what new chemicals are or are not nanomaterials.

Even more importantly, because TSCA defines a chemical only by its molecular structure, many, perhaps most, nanomaterials are considered existing chemicals, not new ones. This is because many nanomaterials have the same molecular structure as existing bulk chemicals. Gold nanoparticles, for example, have the same molecular structure as a bar of gold, even though they may have radically different chemical and physical properties. This is important because, as noted above, the TSCA provisions relating to existing chemicals have mostly been rendered inoperative. The "significant new use" provisions of TSCA may provide a partial way around this obstacle, but EPA has not chosen to use these provisions. In sum, TSCA, at least as currently interpreted by EPA,

cannot regulate most nanomaterials as new chemicals and it cannot regulate any chemicals if they are not defined as new.

The definitional problem is reinforced by a volume exemption that EPA has applied to TSCA. Basically, chemicals manufactured in volumes less than 10,000 kilograms (about 11 tons) are excluded from most of TSCA's provisions. The 10,000 kilo figure is ridiculously large when applied to nanomaterials, where one kilo is a fairly large amount. However, this exemption is not in the law itself, so EPA could and should modify it administratively.

Another TSCA problem raised by nanotechnology, as well as by other new technologies such as synthetic biology, is created by TSCA's limited ability to require information on the new chemical notices it receives. Most of the new chemical notices contain no testing information. The only information they contain is the chemical structure of the substance. Given this situation, EPA has resorted to using what is called "structure-activity relationship" or SAR analysis. SAR compares the molecular structure of the new chemical to the molecular structure of similar existing chemicals and uses the risks of the similar existing chemicals to predict the risks of the new chemical. Under the best of circumstances this approach has limitations, but it is useless when there are no similar chemicals with known risks, as is the case with nanomaterials..

The issues raised by TSCA's application to nanotechnology raise the more general issue of the capability of existing regulatory systems to deal with the new technologies that are emerging at an accelerating pace. Nanotechnology is one example. Another is the rapidly developing field of synthetic biology, which gives scientists the ability to design genetic sequences from scratch and use the sequences to create new custom microbes, such as those that could be used to make biofuels. A particular challenge for EPA will be its ability to assess the risks of future complex synthetic organisms that have no counterpart in nature, and TSCA does not provide adequate authority or tools to address these risks.

There is a large mismatch between the current regulatory system and the characteristics of 21st century science and technology. This mismatch will grow rapidly. I urge this committee to devote some time and effort to considering what new oversight and regulatory approaches are needed. Considering TSCA's effectiveness is a step in the

right direction, but over the long run we are going to need whole new approaches to deal with the new technologies.

TSCA is not serving us well now and it will not in the future. The committee deserves praise for giving its attention to TSCA, and I hope that your efforts result in constructive changes to the law.